

Notice of Allowability

Application No.

10/730,231

Examiner

Janet L. Coppins

Applicant(s)

ADAMS ET AL.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicants' Amendment of April 13, 2005.
2. ☒ The allowed claim(s) is/are 1-24.
3. ☒ The drawings filed on 08 December 2003 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

DETAILED ACTION

Claims 1-24 pending in the instant application.

Information Disclosure Statement

1. Applicants' Information Disclosure Statement (IDS), filed April 13, 2005, has been considered by the Examiner. Please refer to the attached copy of Applicants' PTO-1449 form, submitted herewith.

Response to Amendment

2. Receipt is acknowledged of Applicants' Amendment, submitted April 13, 2005, which has been reviewed by the Examiner and entered of record in the file.

3. Accordingly, claims 1 and 14 have been amended.

Election/Restrictions

4. The Restriction Requirement has been overcome via Applicants' cancellations and amendatory changes to the claims.

Allowable Subject Matter

5. Claims 1-24, are allowable, in newly amended form.

The following is an examiner's statement of reasons for allowance: This invention relates to novel peptidyl boronic acid ester compounds and their pharmaceutical compositions that exhibit proteasome inhibitory activity. The instant application is a CON of application No. 10/392,165, now Pat. No. 6,747,150, which is a CON of application No. 10/125,997, now Pat. No. 6,617,317, which is a CON of application No. 10/100,295, now Pat. No. 6,548,668, which is a CON of application No. 09/953,540, now Pat. No. 6,465,433, which is a CON of application No. 09/490,511, now Pat. No. 6,297,217, which is a DIV of application No. 09/085,404, now

Art Unit: 1626

Pat. No. 6,066,730, which is a DIV of application No. 08/549,318, now Pat. No. 5,780,454, which is a CIP of application No. 08/442,581, now Pat. No. 6,083,903, which is a CON of application No. 08/330,525, now abandoned. The allowable compounds in this case are limited to peptidyl boronic acid compounds according to the formula (1a) of claim 1, wherein "P" is hydrogen or an amino group protecting moiety, and the " $B^1(-R^1)X^1$ " moiety is absent, which differentiates the instant claims from the related applications. The preferred amino group protecting moieties for "P" are described on page 12 of the specification. The claimed compounds are found allowable because certain peptidyl boronic acid compounds are known to those skilled in the art as renin inhibitors. However the aspect of preparing the instant boronic acid compounds, that contain a central amino-carboximide-boronic ester moiety, is novel and unobvious. The closest of prior art fails to teach or render obvious the preparation of the aforementioned compounds that contain the same peptidyl-boronic acid ester structure as described above. For example, Kleeman et al disclose similar peptidyl boronic acid compounds that are potent renin inhibitors, however there is no overlap with the instantly claimed compounds since Kleeman et al teach that when " A^2 " is absent, " A^1 " may not be a radical of the formula (II), which differentiates them from the instant claims. Therefore, the prior art of record does not teach or fairly suggest the instant claimed peptidyl boronic acid ester compounds and compositions.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Art Unit: 1626


Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Coppins whose telephone number is 571.272.0680. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571.272.0699. The fax phone number for the organization where this application or proceeding is assigned is 571.272.8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Coppins
July 18, 2005



Joseph K. McKane
Supervisory Patent Examiner, Art Unit 1626